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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,478

02/25/2002

John L. Ricci

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06/22/2006

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/081,478	<b>Applicant(s)</b> RICCI ET AL.	
	<b>Examiner</b> Javier G. Blanco	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-27 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 21-27 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2006 has been entered.

### ***Response to Amendment***

2. Applicants' cancellation of claims 1, 3, 4, 6-8, and 11-20 in the reply filed on May 30, 2006 is acknowledged.
3. Applicants' addition of claims 21-27 in the reply filed on May 30, 2006 is acknowledged.

### ***Priority***

4. Recently added independent claim 21 (broader version of previous claim 1) is directed to subject matter disclosed in parent application 09/500,038 (now US 6,419,491 B1), filed February 8, 2000. According to the Applicants (see Response filed May 30, 2006) said subject matter of claim 21 was also disclosed/described in Application No 08/146,790 (now abandoned), filed November 2, 1993. The Examiner did not have a copy of said application at hand (available). The Examiner will presume that the subject matter of claim 21 was disclosed in Application No 08/146,790. The Examiner respectfully requests the Applicant to submit a copy of Application

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No 08/146,790. Thus, pending reviewing of Application No 08/146,790, the effective filing date for the subject matter of claim 21 is November 2, 1993.

5. It is noted that the present Application is a continuation-in-part of US 6,419,491 B1. The subject matter of claims 22-27 was not disclosed/described in US 6,419,491 B1. Therefore, the effective filing date for claims 22-27 is considered to be February 25, 2002.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claim 1 of the application and (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569 lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569 is in effect a “species” of the “generic” invention of claim 1. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 is anticipated by (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569, it is not patentably distinct from (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569.

8. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Application No. 09/784,284. Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications claim an implantable article comprising microtexturized surfaces comprising grooves and ridges having a width and height of about 2 to about 10 micrometers (microns). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

9. Claims 22 and 23 are objected to because of the following informalities: regarding each of claims 22 and 23, please substitute "said article" (see line 1) with --wherein said article--.
- Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 21 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892).

Referring to Figures 4A-4H, 5A-5F, 6A-6E, and 7-9, Naiman et al. disclose an implantable article (**Figure 7:** implant 46; **Figure 8:** hip prosthesis 54; **Figure 9:** dental implant 55) comprising microtextured upper (Figure 7: grooves 44 and ridges 45 on upper surface; Figure 8: zone II; Figure 9: zone 61) and lower (Figure 7: grooves 48 and ridges inside cavity 47; Figure 8: zone I; Figure 9: zone 62) surfaces; said upper surface comprising grooves and ridges having a width and a height of about 2 to about 10 microns (see columns 9, 10, and 16), *proportioned to* (emphasis added to intended use) a cell morphology of soft tissue cells (see columns 11-13); and said lower surface comprising grooves and ridges having a width and a height of about 8 to about 25 microns (see columns 9, 10, and 16), *proportioned to* (emphasis

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added to intended use) a cell morphology of bone tissue cells (see columns 11-13); said article being substantially planar and biocompatible. Nayman et al.'s invention is applicable to various implants/prostheses or substrates

a. It should be noted that, for both the upper surface and the lower surface of the article, independent claim 21 claims "grooves" and "ridges". In other words, there is no difference in shape between both upper and lower surfaces. Also, the claimed range of the width and height (depth) of the "grooves" and "ridges" of the upper surface overlaps the claimed range of the width and height (depth) of the "grooves" and "ridges" of the lower surface.

b. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892) in view of Curtis et al. (US 5,833,641; cited in Applicants' IDS).

Naiman et al. disclose the invention as claimed in claim 1. Although Naiman et al. disclose/suggest their invention as applicable to various implants/prostheses and substrates (e.g., sheets), they did not particularly disclose their article as bioabsorbable article having a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm<sup>2</sup>. However, this is already known in the art.

Curtis et al. disclose a cell growth orienting means either integrally formed or provided on the surface of implants/prostheses (see column 2, lines 31-46), or as a bioabsorbable/biodegradable membrane/sheet/substrate (see Figure 1; column 2, lines 31-46; column 3, line 55 to column 4, line 2) wherein the biodegradable membrane/sheet/substrate defines a width of between about 200 microns and about 500 microns and a weight in a range of one to five grams/cm<sup>2</sup> (see column 3, lines 49-54; see column 4; see entire document) in order to provide a flexible nature to the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses (see columns 2-4). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an implantable substrate having cell growth orienting means, a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm<sup>2</sup>, as taught by Curtis et al., with the implantable article (e.g., substrate) of Naiman et al., in order to provide a flexible nature to the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses. Also, it has been held that where the general conditions of a claim

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are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 13, 2006



David H. Willse  
Primary Examiner